NIH MANUAL CHAPTER

54517 - REVIEW OF PROGRAM PROJECT GRANT APPLICATIONS

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A. Purpose

This chapter explains NIH policy, procedures, and responsibilities for the review of program project grant applications. It includes the pre-application phase, initial review group (IRG) assignment, preparation for and conduct of initial review (both at the site visit and by the IRG) and preparation of the site visit report and/or the summary statement.

B. Applicability

The policy stated herein is applicable to all new, competing continuation, and competing supplemental program project grant applications and provides general guidance which may be useful for the review of other multicomponent grant applications. It is recognized that individual institutes and centers (ICs), while adhering to the general policy stated herein, may have institute-specific guidelines in order to best serve the mission of their particular IC.

C. Background

A program project (P01) grant is an award that is based on the concept that projects closely related to a central theme can be conducted more effectively and efficiently through a coordinated collaborative or multidisciplinary approach that may utilize common resources, facilities, and instruments. Foreign institutions may not be awarded grants for program projects. Whereas the initial review of individual research project (R01) grant applications is usually managed by the Division of Research Grants (DRG), the review of P01 applications is usually managed by the ICs. Over the years, the philosophy of P01 review has evolved so that each research project within the P01 award must be supportable on its own merit, recognizing that the scientific merit of each research project is assessed independently, as well as within the context of the whole program. This manual chapter describes the program project peer review process to promote fair and uniform procedures.

D. References

1. Code of Federal Regulations, Title 42, Part 52h, Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects.

2. NIH Manual 1805, Use of Advisors in Program and Project Review and Management.

3. NIH Manual 4104, NIH Research Grants to Foreign Institutions and International Organizations.

4. NIH Manual 4107, Review of Applications and Award of Grants Involving Human Subjects.

5. NIH Manual 4110, Program Announcements (PAs) and Request for Applications (RFAs).

6. NIH Manual 4205, Role of the Principal Investigator on Research Projects Supported by NIH.

7. NIH Manual 4206, Responsibility for Care and Use of Animals.

8. NIH Manual 4510, Referral and Initial Review of NIH Grant and Cooperative Agreement Applications.

9. NIH Manual 4511, Project Site Visits Involving Review of Grant and Cooperative Agreement Applications.

10. NIH Manual 4512, Summary Statements.

11. NIH Manual 4513, Review of NIH Programs and Grant and Cooperative Agreement Applications by National Advisory Councils and Boards.

12. NIH Manual 4514, Role of Staff at Peer Review Advisory Committee Meetings and Exchange of Information Among Initial Review Groups and Grants Management Staffs.

13. I&I Memorandum No. OER 90-05, December 11, 1990, Inclusion of Women and Minorities in Study Populations. (This will be issued as NIH Manual Chapter 7110, Inclusion of Minorities and Women as Subjects in Research).

E. Definitions

E.1. Ad Hoc IRGs - These are special review groups constituted by DRG or an IC to perform a single, specific, short-term review task, after which they are disbanded. With the establishment of Special Emphasis Panels (SEPs), it is expected that Ad Hoc IRGs will no longer be used.

E.2. Component - A research project, core or other unit for which a detailed budget is included in the P01 grant application.

E.3. Initial Review Group (IRG) - An advisory group composed primarily of non-Federal scientific experts who conduct the scientific and technical merit review of grant and cooperative agreement applications. Initial review groups may be (1) chartered NIH advisory committees, managed by either DRG or ICs or (2) ad hoc groups.

E.4. National Advisory Council/Board - An advisory committee composed of both scientists and lay members, which has broader responsibility than IRGs. The members are outstanding authorities knowledgeable in relevant IC programmatic areas, are aware of the roles of the diverse institutions in biomedical and behavioral research, and are especially concerned with the health needs of the American people. Councils/Boards perform the final advisory review of grant and cooperative agreement applications and advise on matters of significance to the policies, missions, and goals of the relevant IC.

E.5. P01 - The NIH activity code that identifies a program project application or grant.

E.6. Principal Investigator (PI) - For the purposes of this manual chapter, the one person designated by, and responsible to, the applicant/awardee organization for the scientific and technical direction and proper conduct of all components of the program.

E.7. Program Project Grant (P01) - An assistance award for the support of a broadly based multidisciplinary research program that has a well-defined central research focus or objective. The grant supports a minimum of three interrelated projects that contribute to the program objective. The grant may also include support for common supporting or shared resources (cores) required for the conduct of the component research projects. Interrelationships between component projects are expected to result in a greater contribution to the program goals than if each project were pursued separately.

E.8. Project Leader - The investigator responsible for the scientific direction and conduct of an individual research project or core component of a program project.

E.9. Request for Applications (RFA) - A formal, published invitation by NIH for grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program purposes, with set-aside funds and/or an award number goal.

E.10. Scientific Review Administrator (SRA) - An NIH scientist administrator responsible for the organization and management of the initial review process for applications.

E.11. Special Emphasis Panels (SEPs) - These are also chartered IRGs, but they are designed to be more flexible than conventional study sections or review committees. SEPs have a fluid membership, with members designated to serve for individual meetings rather than for fixed terms of service.

F. Policy

The NIH is committed to objective, quality peer review of grant applications submitted by the scientific community and to the principle of funding on a competitive and equitable basis.

To maintain an objective review process separate from programmatic considerations and to avoid real or apparent conflicts of interest, review staff must be organizationally independent from the pertinent program units. Review staff shall have responsibility and autonomy for the conduct of initial review activities.

During site visits and IRG meetings, discussions of IC policy concerning paylines, percentiles and priority scores, as well as evaluative comments, may bias review, and, therefore, such discussions must be avoided by NIH staff throughout the review process.

Site visit teams and/or initial review groups for program project applications must reflect a balance in terms of experience, expertise, and specialty so as to afford peer review of the separate elements of the applications and their integration into the overall research program. NIH staff, however, may not participate in evaluating or recommending on

applications or projects for which they have had or may have other selection, award, or administration responsibilities.

Site visit reports and summary statements for program project applications should present the review findings and recommendations in a uniform manner throughout the various review units of the NIH, follow the format prescribed in NIH Manual 4512, and reflect evaluations of the individual components as well as of the total program.

To be eligible for an award, a P01 must consist of three or more projects with significant and substantial merit whose interrelationships will result in a greater contribution to program goals than if each individual project were pursued separately.

G. Responsibilities

G.1. General - The review responsibilities of chartered NIH committees are defined by their authorizing charters. The establishment, renewal, and modification of all chartered NIH advisory committees are governed by the Federal Advisory Committee Act and pertinent implementing government-wide and Departmental regulations.

Continuing evaluation of the soundness and objectivity of the NIH initial review process is the responsibility of the Deputy Director for Extramural Research and is shared with the Director, DRG. This responsibility includes the right to send representatives to IRG meetings and site visits.

When an application is assigned to an IC for review, that organization accepts full responsibility for ensuring quality and objectivity in the evaluation, for arranging all aspects of the review and its documentation, and for ensuring that conflicts of interest are avoided. If an IC plans a review employing procedures which constitute a significant departure from currently accepted peer review practices, these plans are to be discussed with the Director, DRG and the Deputy Director for Extramural Research (DDER) in advance of the review. In Addition, the IC Grants Management Officer (GMO) must be consulted when an IC anticipates a deviation from standard review procedures.

G.2. Institute, Center and Division Staff - Review staff in the ICs are organizationally independent of the pertinent IC program units. (See F. Policy, above.) Review staff are responsible for managing the scientific and technical review of P01 applications, including the selection of reviewers, management of site visits and IRGs and the documentation of the site visit team and IRG findings and recommendations. Review staff should keep reviewers informed of new developments in the review process, policies and regulations, and current statistics.

Program staff are responsible for the development and management of initiatives and programs of research sponsored by the IC. They are expected to advise and inform prospective applicants about program areas of relevance to that particular IC, guidelines for the P01 application, the appropriate format, and receipt dates.

Grants management staff are available as a resource to the SRA, program staff, and prospective applicants in the area of fiscal, administrative, and grants policy matters.

G.3. Communications - Staff responsibilities for communications with applicants shift during the various phases of the review process. Prior to submission of the application, program staff are the appropriate contact. Subsequent to submission and assignment of the application, and until initial review has been completed, all contacts are made through the SRA. Following the IRG meeting, program staff again is the focal point of communications with the Principal Investigator.

H. Conflict of Interest

Every effort is made to avoid both the fact and appearance of conflict of interest in obtaining advice concerning P01 applications. The policies, responsibilities, and guidelines set forth in NIH Manual 1805 apply to all review advisors. NIH Manual 4510 emphasizes the need to avoid the appearance of conflict of interest in all aspects of review.

In addition to the policy and guidance contained in the aforementioned chapters, the following guidance shall also pertain:

- Because the size and complexity of P01 applications often require the conduct of site visits, the SRA must pay special attention to potential conflicts of interest concerning ad hoc consultants for site visit teams.

- SRAs usually may not manage or conduct the initial review of applications from members of their own committees; nor may the chairpersons of disqualified committees chair those reviews. (See NIH Manual 1805 F.2.c.)

- Principal investigators (PIs) may not participate as consultants in reviews of any P01 application which is being reviewed by that IC during the same review round as their own.

I. Distinguishing Features of a Program Project Grant

The following features characterize P01 grants:

- There must be a unifying well-defined goal or problem area of research to which each project relates and contributes, thereby producing a synergistic research environment that allows each research effort to share the creative strengths of the others. There is the expectation that support of interrelated projects and collaborating investigators would yield results beyond those achievable were each project pursued separately and without formal interaction among the participating investigators.

- The PI must possess recognized scientific and administrative competence and must show a substantial commitment of time and effort to the program and exercise leadership in the maintenance of its quality. NIH policy on minimum effort by PIs is outlined in NIH Manual 4205. In addition, some ICs may specify a different level of effort for P01s; this underscores the need for communications between NIH staff and applicants during the pre-application stage.

- A program project must contain a minimum of three component research projects that are judged to have significant and substantial scientific merit on their own as well as being complementary or contributory to the central theme of the P01. The optimum size may vary, depending upon IC missions and goals. A number of ICs have dollar limits on P01 applications.

- Program projects usually require the participation of established investigators in several disciplines or investigators with special expertise in several areas of one discipline. All investigators must contribute to, and share in, the responsibilities of fulfilling the program objective.

J. Review Criteria

J.1. Review Criteria for Individual Research Projects:

- Scientific, technical, or clinical significance and originality of the proposed research; each project should be rated on its own merit;

- Appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;

- Qualifications and research experience of the individual project principal investigator and staff, particularly but not exclusively in the area of the proposed research;

- Availability of resources necessary for the research;

- Appropriateness of the proposed budget and timetable in relation to the scope of the proposed research;

- The adequacy of the proposed means for protecting against or minimizing potential adverse effects upon humans, animals, and/or the environment; and

- When human subjects are involved, the adequacy of plans to include women and minorities in the study design and the potential of that design to address the scientific question(s) addressed.

J.2. Review Criteria for Individual Cores:

- Utility of the core to the program project; each core should provide essential facilities or service for two or more projects judged to have substantial scientific merit;

- Quality of the facilities or services provided by this core (including procedures, techniques, and quality control) and criteria for prioritization of usage;

- Qualifications, experience, and commitment of the personnel involved in the core; and

- Appropriateness of the budget.

In the reviewing of a competing continuation (renewal) application, the progress made during the past period of funding is also an important consideration in the review of projects and cores.

J.3. Review Criteria for Overall Program Project

The relationship and contributions of each research component and core (excluding those removed through recommendations by the IRG) to the overall theme of the program project are discussed and evaluated (these determinations must be clearly and specifically outlined in the summary statement). This should be a separate consideration which is not influenced by the merit ratings of the individual projects. Although projects not recommended for inclusion in the program automatically are removed from consideration as part of the overall program project, such projects will reflect on the leadership capabilities of the principal investigator and shall be considered in the overall merit.

The overall program project application is evaluated considering the remaining projects, supporting cores, and the administrative structure. For the program project to receive a priority score, it must consist of at least three projects (each found to have significant and substantial merit) for the duration

of the project period. Each core must provide essential functions or services for at least two of these projects.

Specific factors to be evaluated in the consideration of the overall program project are as follows:

J.3.a. Scientific Considerations - The following criteria must be evaluated:

- Scientific merit of the program as a whole, as well as that of individual projects;
- Significance of the overall program goals;
- Scientific gain of combining the component parts into a program project (beyond that achievable if each project were to be pursued separately);
- Cohesiveness and multidisciplinary scope of the program and the coordination and interrelationship of all individual research projects and cores to the common theme;
- Leadership and scientific ability of the principal investigator/program director and his or her commitment and ability to develop a well-defined central research focus and to devote adequate time and effort to the program; and
- Past accomplishments of the program or a demonstrated ability in mounting similar programs.

Additional criteria for competing continuation (renewal) applications include:

- Progress and achievements specific to this program project since the previous competitive review and the documentation through publications, conferences, etc.; evidence that collaboration has occurred;
- Evidence that the previous specific aims, as funded, have been accomplished and that the new research goals are logical extensions of ongoing work;
- Previous performance and estimated use of the core(s); and
- Justification for adding new projects or cores or for deleting components previously supported.

J.3.b. Administrative Considerations

For all program project applications (new, competing continuation, and competing supplemental), in addition to evaluating the scientific components, the review also will assess:

- Academic environment and resources in which the research will be conducted, including availability of space, equipment, human subjects, animals, or other resources as required, and the potential for interaction with scientists from other departments;

- Institutional commitment to the requirements of the program, including fiscal responsibility and management capability of the institution to assist the principal investigator/program director and his or her staff in following HHS, PHS, and NIH policy;

- Administrative planning and leadership capability to provide for internal quality control of ongoing research, allocation of funds, enhancement of internal communication and cooperation among the investigators involved in the program, and replacement of the principal investigator/program director if required on an interim or permanent basis;

- Appropriateness of the budget in relation to the proposed program; and

- Human subjects protection, animal welfare, and biohazard issues.

J.4. Recommendations Regarding Budgets

The site visit team and/or IRG may recommend adjustments, as judged appropriate, in the requested budgets and periods of support for the components of P01s which are deemed to have significant and substantial merit. It is important that IRG members examine proposed budgets closely.

K. Implementation

K.1. Pre-application Phase - Communications between a potential principal investigator and IC program staff at the pre-application planning phase will serve to 1) advise the applicant concerning the areas of program interests of the IC; 2) facilitate the receipt of a well organized, tightly focused application, and 3) ensure that the application conforms to established guidelines and criteria for a P01 application.

Program staff are particularly cognizant of the scope of their programs and of the P01 guidelines and are especially qualified to advise applicants concerning the preparation of a complete and well-developed application. The initial contact with NIH program staff is the responsibility of the potential applicant and should be made as early as possible. This interaction may take the form of correspondence, such as a letter of intent, telephone conversations, applicant visit to the NIH, and/or an on-site visit by IC staff to the applicant institution. Such communication will enable the staff to discuss issues such as the need for integration of all projects into the theme of the overall program, the established review guidelines, the proper format of the application, and the necessary relevancy of the proposal to the programs supported by the IC.

Some ICs may request the development of P01 applications in relation to a particular research area. This need will be conveyed to the scientific community through an RFA or program announcement. Policies and procedures regarding such program initiatives are outlined in NIH Manual 4110.

K.2. Assignment to an IRG

K.2.a. Receipt - DRG is the central receipt point for all P01 applications.

K.2.b. Assignment - Assignments to IRGs for review and to ICs for scientific management are based on two publications: "Referral Guidelines for Initial Review Groups of NIH" and "Referral Guidelines for Funding Components of the PHS", respectively. Authority for these assignments rests with the Director, DRG, or designee.

K.3. Preparation for the Review - From the time an application is submitted to the NIH and assigned for initial review, until initial review by the IRG is completed, all correspondence and communications between the PI or the institution and the NIH must be through the SRA responsible for the initial review. Upon receipt of an application, the SRA reviews it for conformance to NIH policies and IC guidelines. If the application fails to comply, it is returned by the DRG to the applicant institution. The SRA is also responsible for contacting the PI to obtain additional information judged necessary for adequate review. In addition, the SRA is responsible for judging the need for a site visit. A site visit is not a prerequisite for consideration of a P01 grant application by an IRG. All references to "site visit" in this document also pertain to applicant interviews, where the review is not held on-site.

K.3.a. Selection of the Site Visit Team

K.3.a(1). Guidelines - The size and composition of each site visit team are determined by the particular details of the application; it is the responsibility of the SRA to make these determinations based upon a thorough review of the application and suggestions from program staff. Where the site visit team will present its findings and recommendations to a chartered IRG, appropriate members of that IRG are included on the site visit team. The chairperson of the site visit team, usually a member of the chartered committee, should be a senior investigator experienced in the review of complex multidisciplinary applications and generally knowledgeable in the scientific areas to be reviewed. Where no subsequent review by a chartered committee is involved, due to conflicts of interest, requirements for particular expertise, or other cause, the site visit team is constituted as a Special Emphasis Panel (SEP).

The composition of the site visit team should reflect a balance in terms of experience, expertise, and specialty so as to afford peer review of the separate elements of the application. The number of reviewers on the site visit team generally ranges from 5 to 15. These reviewers should be recognized investigators in the relevant scientific disciplines and, where necessary, qualified administrators or specialists in appropriate fields. A consultant experienced in fiscal and management administration is sometimes necessary when large or complex programs are reviewed.

K.3.a.(2). Resources Available - In identifying prospective qualified reviewers, SRAs should take full advantage of the many resources available, including existing name files of experienced reviewers, lists of grantees and contractors, computerized data bases, and consultation with program and review staff, committee members, and recognized authorities in the scientific community. The SRA, as well as program staff, will identify reviewers who, because of collaboration, affiliation, or bias, should be excluded from the review.

K.3.b. Communication with the PI Regarding Site Visit Arrangements - Following his or her administrative review of the application, the SRA calls the PI to establish an acceptable date and time frame for the site visit. This discussion should also include:

- the prospective agenda for the site visit;
- the specific disciplines or specialty areas of expertise which the PI feels are required to review the application properly. Names of potential reviewers must not be either directly or indirectly solicited (or accepted) from the applicant; and
- individuals who, in the opinion of the PI, may not be able to give an unbiased review, and who should not be considered for the site visit team. The PI should request the exclusion(s) in writing, including a brief statement expressing his/her concerns. Full consideration should be given to valid reasons presented by the PI for requesting that a particular consultant not be invited.

When the arrangements for the site visit are completed, the SRA advises the PI, in writing, of the details, including the roster of the site visit team, the agenda, and a list of technical or administrative deficiencies apparent in the application.

K.3.c. Communications with Reviewers - Discussion between the SRA and each potential consultant centers about the primary research focus of the P01 application, the PI, and the specific research and/or resource area(s) of relevance to the prospective reviewer. The date, time frame, and potential conflicts are considered, and a commitment is obtained. When the site visit team is completed, a roster is prepared. The roster, appropriate guidelines, the application, appended material, site visit agenda, and details of arrangements for the site visit are forwarded by the SRA to members of the site visit team. The SRA identifies reviewers for each project and core and advises them of their responsibilities.

K.3.d. Communications with Other Extramural Staff - Shortly after receipt of the application, the SRA contacts appropriate IC staff for supplemental information, recommendations for prospective reviewers, and information on site visit plans. Copies of the application and relevant materials provided to the members of the site visit team also are provided to the staff who will be present at the site visit. Program and/or grants management staff should discuss with the SRA any unusual features of the application which

might require additional material for reviewers, or any special problems that they anticipate in the review of the application. Neither program nor grants management staff may communicate directly with actual or potential reviewers about the review. All communications should be through the Scientific Review Administrator. This includes communications with the PI as well as with reviewers.

K.4. The Site Visit - A P01 application should contain sufficient information for its review without a site visit. When a site visit is deemed necessary, its purpose usually is to gather information not obtainable in writing or by telephone. The site visitors are particularly interested in new information developed since the application was written. They may also wish to obtain additional information about further aspects of research rationale, future research plans, anticipated problems, and the interrelationships of the constituent components to form a P01 (amended applications, supplemental requests, and certain other applications usually are reviewed without site visits). Site visitors should not ask leading questions so as to direct the PI's line of research.

The SRA is responsible for ensuring that the review is conducted in accordance with NIH policies. Discussion which might bias the peer review process is specifically excluded, such as IC paylines, fundable priority scores, etc. NIH staff will avoid evaluative comments about the application or the investigators.

K.4.a. Pre-Site Visit Meeting - The SRA holds a briefing session before the on-site visit, opening this session with the introduction of the site visitors and NIH staff. The SRA discusses review procedures and criteria, the fact-finding role of the site visit team, the need for a well documented site visit report/summary statement, the role of the report in the review process, and the functions of the staff. The SRA also presents an explanation of conflicts of interest, implications of the Privacy Act, the need for confidentiality of the proceedings and materials, and other policy and logistic matters.

The IC GMO is responsible for monitoring the objective review process to ensure that all applicable PHS requirements have been carried out. When practicable, the GMO shall attend grant application review panel meetings in an advisory capacity. When requested, the GMO shall interpret grants management policies to panel members. In addition, when any actions they propose conflict with existing grants management requirements, the GMO shall so advise the members.

The chairperson leads a discussion of the site visit agenda and a systematic discussion of each component of the application, finalizing the assignment of various components of the application to members of the site visit team. The SRA is the resource person for the site visit team with respect to NIH review policies, guidelines, rules, regulations, options available, procedures, etc. The program staff representative serves as a resource person, as needed, concerning the history and development of the program, changes in program direction, and other relevant program matters.

K.4.b. On-Site Visit - The primary focus during the site visit is on the research proposed rather than on past progress, although for competing continuation applications past progress is an important review criterion. It should be explained to the PI that the reviewers have studied the grant application in detail and that there should be no repetition of its contents.

As required for the review, each component of the program should be presented with appropriate professional personnel involved with that component being present. The presentation of each project should be held to a reasonable time period, and adequate time should be allotted for questions and answers. Once the site visitors have gained a common base of information, it may be desirable to divide the site visit team into groups to tour certain specialized facilities and/or pursue a particular question with a project leader. Executive sessions are held at various times during the site visit. A final meeting of the site visitors with the PI (and others as required) is usually conducted to provide the PI and reviewers with an opportunity for clarifying unresolved issues.

K.4.c. Post-Site Visit - Following the site visit, the reviewers meet for intensive discussion of the application and the new information obtained. Each component is discussed, usually under the leadership of its primary reviewer, who also has the responsibility for documenting the discussion, evaluation, and recommendations. The site visitors discuss each component on its own merit, culminating in a merit rating. For individual research projects, this could be either a numeric score or a descriptor (such as Outstanding, Excellent, Very Good, Good or Acceptable). Although cores usually are assigned descriptors, a numeric score may be assigned if the core includes a research component as part of its role as a shared resource. If a component does not have significant and substantial merit, it should be identified as: not recommended for further consideration (NRFC). Each research project involving human subjects, as defined in Manual 7110, will

also be assigned separate codes for gender and minority representation, as part of the review.

After discussion of the individual components is completed, the reviewers determine the adequacy of the overall program in terms of the criteria for a P01. If a component is not relevant to the program's theme, it should be deleted from the program. A deleted project retains its merit rating (based on its merit as an individual project), but is removed from consideration as part of the program project.

A merit rating then is expressed for the overall application. For an application that is not recommended for further consideration (NRFC), there is neither a merit rating nor a recommended budget. Appropriate codes for gender and minority representation will be assigned for the overall application if one or more projects are covered by the policy (see NIH Manual 7110).

A narrative critique of each component in the P01 is prepared by the assigned reviewers. At a final session, each of these sections is read to the group and modified as needed to include all major points raised by the group. The SRA collects the sections and is responsible for developing the overall report documenting the review.

K.4.d. Site Visit Report/Summary Statement - The findings and recommendations of the reviewers are summarized in a written report which accurately conveys the evaluation of the application; this report is the site visit report when transmitted to the parent IRG for further consideration and to complete initial review; it is the summary statement when submitted for advisory council/board consideration. The outline for the site visit report is the same as that for the summary statement (NIH Manual 4512).

K.5. Review of the Application and Site Visit Report by the IRG - The site visit report developed by the reviewers and edited by the SRA is distributed to the members of the IRG for their consideration prior to the committee meeting.

The primary responsibility of a chartered committee is the scientific evaluation of grant applications. Full consideration is given to the findings and recommendations presented in the site visit report. An element of chartered committee reviews is the reassurance that the criteria for P01s (see Section I.) are satisfied.

The SRA assures effective and accurate transmission of the site visit findings to the committee through extensive participation of committee members who took part in the site visit. The review may also require the participation at the committee meeting of one or more site visitors as ad hoc reviewers. For applications which did not require a site visit, the expertise of the committee may be augmented through the use of mail reviews and/or ad hoc reviewers. After a thorough discussion of the application, each committee member privately gives a priority rating to each application unless the application is not recommended for further consideration (NRFC) or recommended for deferral. The overall priority rating reflects the assessment of the scientific merit of the individual projects and the evaluation of the application as an integrated program, and is based on the scope of work as recommended by the IRG. If reviewers judge that inclusion of components of inferior scientific merit in the original application reflects deficient scientific judgment on the part of the Principal Investigator, the reviewers shall reflect those concerns in assigning their rating. The individual components which are deemed to be of significant and substantial merit may each be rated with a numeric score, or with an evaluative adjective.

K.6. The Summary Statement - The summary statement presents the critique, actions, recommended budget, and priority score from the IRG. After the percentile value is added, the summary statement is transmitted for the IC Council/Board review and, in accordance with NIH policy, to the PI before the Council/Board meeting. Detailed guidance on the content and preparation of Summary Statements may be found in Manual 4512.

K.7. Feedback to Site Visitors and to the IRG - Following the Council/Board meeting, the SRA may provide feedback to the site visit teams as to the status of the applications in whose reviews they participated. The feedback letter may include the IRG action and whether the Council/Board concurred with it, but statements concerning funding status are to be avoided. Members of the chartered IRGs are generally similarly informed at their next meeting. Refer to Manuals 4513 and 4514.

K.8. Competing Supplemental Grant Applications - Supplemental grant support is sometimes necessary for the successful completion of an ongoing P01.

Supplemental applications to P01s will be accepted only under the following circumstances:

- When a component research project was recommended for less time than was the rest of the P01 grant in order to permit an early assessment of progress.

- In response to well defined program initiatives and/or public health emergencies.

- When a persuasive case can be made that the additional or expanded project will significantly improve the scientific quality of the entire program.

The competing supplemental application must contain sufficient detail of both the ongoing program and the added research effort to permit an adequate evaluation of the requested expansion of the overall program. Such supplemental requests are not appropriate when the purpose is solely to restore, to the full IRG- recommended level, awards that were administratively reduced by the funding agency. The IRG will assess the merit of the application as an essential element in the context of the entire program.

L. Records Retention and Disposal

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual 1743, Appendix 1, "Keeping and Destroying Records," item 4000, which covers NIH Grants and Awards. Refer to the NIH Chapter for specific disposition instructions.